K002445

JAN 31 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

Medtronic Physio-Control
LIFEPAK® 12 defibrillator/monitor series with IP Monitor

SUBMITTER INFORMATION

A.	Company Name:	Medtronic Physio-Control
B.	Company Address:	11811 Willows Road Northeast P.O. Box 97006 Redmond, WA 98073-9706
C.	Company Phone: Company Fax:	(425) 867-4000 (425) 867-4121
D.	Contact Person:	Bob Zito Staff Engineer, Regulatory/Standards Medtronic Physio-Control
E.	Date Summary Prepared:	August 4, 2000

DEVICE IDENTIFICATION

The device that is the subject of this premarket notification is the Medtronic Physio-Control LIFEPAK® 12 defibrillator/monitor series. An invasive pressure (IP) feature has been added to the device. The LIFEPAK® 12 defibrillator/monitor series components are classified by FDA as follows:

- Computer, Blood Pressure, Class II (870.1110), 74 DSK
- Low Energy DC Defibrillators (including paddles), Class II (870.5300), 74 LDD
- Cardiac Monitors (including Cardiotachometers and Rate Alarms), Class II (870.2300), 74 DRT

- External Transcutaneous Cardiac Pacemakers (non-invasive), Class III (870.5550), 74 DRO
- Oximeter, Class II (870.2700), 74 DQA
- Automated External Defibrillator, Class III, 74 MKJ
- Interpretive ECG, Class III, 74 LOS
- Non-invasive Blood Pressure Measurement System, Class II (870.1130), 74 DXN
- Analyzer, Gas, Carbon Dioxide, Gaseous Phase, Class II (868.1400), 74 CCK

SUBSTANTIAL EQUIVALENCE

The intended use and function of the LIFEPAK® 12 IP Monitor are substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Propaq 104 Monitor	Protocol Systems, Inc.	K882085	7-28-88
Passport 2™ Vital Signs Monitor	Datascope	K993531	1-13-2000
Eagle 4000 Patient Monitor	Marquette Electronics, Inc.	K964750	2-21-97

DEVICE DESCRIPTION

The LIFEPAK® 12 IP Monitor is an invasive pressure (IP) monitor that is used for measuring arterial and venous blood pressure. This monitor can also be used to measure intracranial and other physiological pressures using an invasive catheter system with a compatible transducer. It may be used on both the adult and pediatric patients. The IP module in the LIFEPAK® 12 consists of two isolated channels of invasive pressure measurement for use in a variety of hospital and pre-hospital settings. When activated

upon connection of a compatible transducer, the invasive pressure monitor digitally displays arterial and venous blood pressure (systolic, diastolic, and mean), intracranial, and other physiological pressures. An audible alarm is provided, and Quick Set alarm limits are automatically set based on the patient's current vital sign values.

INTENDED USE

Invasive pressure monitoring is intended for use in patients that require continuous monitoring of physiological pressures (e.g., blood pressure) in order to rapidly assess changes in patient condition and/or the patient's response to therapy. It may also be used to aid in medical diagnosis determination.

INDICATIONS FOR USE

The LIFEPAK® 12 IP Monitor is indicated for use in measuring arterial, venous, intracranial, and other physiological pressures using an invasive catheter system with a compatible transducer. It may be used on the adult or pediatric patient.

TECHNOLOGICAL CHARACTERISTICS

The LIFEPAK® 12 IP Monitor employs the same functional technology as the predicate devices.

PERFORMANCE DATA

The LIFEPAK® 12 IP Monitor was tested to assure compliance with various published standards, including IEC 601-2-34, IEC 60601-1, and IEC 60601-1-2. The results of the testing demonstrate that the LIFEPAK® 12 IP Monitor is substantially equivalent to the predicate devices with respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2001

Mr. Robert J. Zito
Medtronic/Physio-Control Corporation
11811 Willows Road NE
P.O. Box 97006
Redmond, WA 98073-9706

Re: K002445
Trade Name: LifePak 12 Defibrillator/Monitor Series with Invasive Pressure Monitor
Regulatory Class: III (three)
Product Code: 74 MKJ and 74 DSK
Dated: November 22, 2000
Received: November 24, 2000

Dear Mr. Zito:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K002445 (To Be Assigned By FDA)

Device Name: LIFEPAK® 12 defibrillator/monitor series with IP Monitor

Indications For Use: The LIFEPAK® 12 IP Monitor is indicated for use in measuring arterial, venous, intracranial, and other physiological pressures using an invasive catheter system with a compatible transducer. It may be used on the adult or pediatric patient.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002445